illuminations

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Building public confidence in COVID-19 vaccines

The COVID-19 pandemic has been a time of great uncertainty and tragedy. Last year there were more excess deaths in the UK than in any year since the Second World War, and in the week that bridged the new year, 1 in 50 people in England tested positive for the virus.

This desperate time has also been marked by rapid scientific advancement. Hailed by government and media alike as 'the way out' of a perpetual cycle of lockdowns and liftings, vaccine development has progressed at a truly impressive pace. At time of writing three vaccines had been approved by the Medicines and Healthcare products Regulatory Agency, with more in the pipeline.

Vaccines are essential tools in the fight to end the disease and return to normality but understandable concerns have been voiced by the public about the speed of their development and approval. How can a process that usually takes so much longer have occurred so quickly? What corners have been cut? Can these vaccines truly be safe? Increasing transparency of the governance of these trials and the subsequent measures taken to optimise safety could allay some of these concerns.

New disease, well-established process

The key functions of any clinical trial are to determine both the efficacy and safety of an intervention. As such, integral to their design are processes to seek out adverse events, and a vast body of trained personnel working to safeguard participants and, ultimately, the public.

Those trials searching for a COVID-19 vaccine are no different, requiring and achieving the same level of rigorous governance and attention to good clinical practice as any other clinical trial.

The ENSEMBLE-2 trial is one such COVID-19 vaccine trial. It examines an adenovirus vaccine developed by Janssen (a subsidiary of Johnson&Johnson) and employs a robust and multi-level approach to elicit any potential dangers.

As in all new endeavours, the involvement of the right personnel is key. COVID-19 might be a new disease but the process of vaccine development is well established. Recruitment of a team experienced in the design and management of vaccine trials has allowed a smooth but expedited set-up of ENSEMBLE-2 trial centres around the world, including across the UK.

As participant numbers increase so too must staff size, so effective training is an imperative. The Barts Health NHS Trust ENSEMBLE-2 centre in London has recruited over 550 participants to date and is currently the largest recruiting centre globally.

The accurate gathering of data concerning any adverse events that occur during a trial is vital. With matters of such importance, an element of redundancy must be built into the system that might not be required in other fields. In ENSEMBLE-2, participants log any adverse events as they arise via an app, triggering a discussion of their symptoms with a trained medical professional so information can be garnered and any relevant advice given.

In addition to this, the app regularly prompts them to complete a questionnaire about their health. To ensure the full capture of adverse events, participants are also contacted at regular intervals by study staff and questioned again. This could be viewed as a duplication (or triplication) of workload, but with matters of public health safety must be our watchword.

The COVID-19 vaccine trials are meeting the same rigorous standards of governance, through an unprecedented global effort to concentrate virtually all research capacity to the pandemic.

Key learning points

Perhaps never before has so much public attention been paid to healthcare innovation. How we execute the development and delivery of COVID-19 vaccines is likely to influence public opinion of the field for decades to come.

Though the pandemic has imbued the search for a vaccine with significant urgency, there are always those who could benefit from rapid delivery of new medical interventions. What lessons can be learnt from this success? How will we apply them in the future?

With the death toll still accelerating, it is paramount that the public believe that these vaccines are safe; widespread uptake is crucial for their success. Good practice in clinical trials is well established, and patient safety is always paramount. These principles have been at the centre of the development of COVID-19 vaccines.

The government should not underestimate the importance of communicating to the public that good governance has not been compromised in the search for a solution.

Illuminations

- It is difficult to overstate the value of timely, effective communication to allay public concerns about any significant medical development – especially one as crucial as the COVID-19 vaccines.
- The rapid timescale of the vaccines coming through clinical trials is not due to reduced governance but due to an absence of delays that normally happen.
- Applying good governance is key to ensuring safety and robustness in any situation, not just research.

If you have any questions or comments about this briefing, please call us on 07732 681120 or email **advice@good-governance.org.uk**